



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,316	04/07/2004	Syed F.A. Hossainy	50623.285	8511

7590 05/15/2007
Cameron K. Kerrigan
Squire, Sanders & Dempsey L.L.P.
Suite 300
1 Maritime Plaza
San Francisco, CA 94111

EXAMINER

LIN, JAMES

ART UNIT	PAPER NUMBER
----------	--------------

1762

MAIL DATE	DELIVERY MODE
-----------	---------------

05/15/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/820,316

Applicant(s)

HOSSAINY ET AL.

Examiner

Jimmy Lin

Art Unit

1762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5-9,11,12,14,16-31,57-62 and 65-70 is/are pending in the application.
- 4a) Of the above claim(s) 6,7,11,12,14,17,20,58,66 and 68-70 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,5,8,9,16,18,19,21-31,57,59-62,65 and 67 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application
- ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/29/2007 has been entered.

Election/Restrictions

2. Newly submitted claims 66 and 68-70 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: blowing gas contemporaneously with applying the substance is a non-elected species in the group containing the elected species of blowing gas subsequent to applying the substance (see paragraph 5 of the Election/Restriction requirement filed 4/5/2006). Additionally, inhibiting the evaporation of the fluid carrier seems to be the result of contemporaneously blowing cold gas with the application of the substance (see, e.g., paragraph bridging pg. 10-11 of present specification) and, thus, is a non-elected species.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, the limitation of modifying a balloon from a hyper-inflated state to a state of intended expanded configuration of claims 66 and 68-70 are withdrawn from consideration as being directed to a non-elected species. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 21-31 and 62 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which

was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

There is no support for reducing the balloon to a collapsed configuration or an under inflated state or deflating the balloon in general in preparation for the intended use of the balloon (claim 21) nor is there support for deflating the balloon at any time (claim 62). The specification only provides support for reducing the balloon size during the modification process or during/prior to the drying process.

There is no support for deflating the balloon after removal of at least some of the fluid. The specification only provides support for deflating the balloon prior to or during the process of removal of the fluid.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 21, 24-26, 28-29, 31, 57, and 67 are rejected under 35 U.S.C. 102(b) as being anticipated by Barry et al. (U.S. Publication 2002/0037358).

Barry discloses a method of modifying a balloon catheter, the method comprising:
inflating a balloon of a catheter to an inflated state;
applying paclitaxel (i.e., a therapeutic drug) in a fluid carrier onto the polyurethane membrane of the balloon catheter;
drying the fluid carrier from the balloon leaving a dry form of the paclitaxel on the surface of the balloon (Example 9).

Barry teaches that the balloon is in its substantially deflated state prior to insertion into a patient (i.e., deflating balloon to a collapsed configuration or an under inflated state in preparation for the intended use of the balloon) ([0046]; Fig. 1b). Paclitaxel is applied onto the

outer surface of a balloon to deposit paclitaxel within the polyurethane coating of the balloon (i.e., within the wall membrane of the balloon) (Examples 9; [0032]).

Claims 25-26: Paclitaxel is saturated (i.e., dissolved) in the carrier fluid.

Claim 28: Paclitaxel is a drug.

Claim 24: Barry does not explicitly teach maintaining the inflated state at the same or generally the same level during the application of the substance to the balloon. However, Barry provides no teaching or reasoning for modifying the inflated state of the balloon during deposition. One of ordinary skill in the art would have inflated the balloon prior to deposition and would not have been concerned with the inflated state during deposition. Therefore, the inflated state of the balloon would have remained substantially the same during deposition because one of ordinary skill would not have actively modified the inflated state.

Claims 29,57,67: Barry does not explicitly teach that the polyurethane membrane of the balloon is porous. However, Barry teaches that the therapeutic drug is impregnated into the polymer. Impregnating involves filling the interstices (i.e., pores) of a layer with a substance. Thus, the polyurethane membrane must necessarily have pores. Additionally, the Applicant relates the amount of pores to the degree of impregnation (see pg. 17, lines 1-5 of present specification).

Barry does not explicitly teach collapsing the pores after applying the substance to the balloon. However, inflating the balloon would have necessarily opened up the pores because the balloon surface stretches during inflation and the pores would have expanded. In a similar manner, subsequently deflating the balloon would have necessarily collapsed the pores.

Claims 31,60: The balloon is inflated prior to deposition.

7. Claims 21 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Sahatjian et al. (U.S. Patent 5,674,192).

Sahatjian discloses a method for coating a balloon of a catheter. The balloon is inflated, coated with a drug, dried, and then deflated. The drug is in a carrier fluid (col. 14, lines 45-63). The drug can be impregnated within the wall membrane of the balloon (col. 11, lines 24-27).

Sahatjian does not teach that the inflated state of the balloon is changed during the coating process. However, Sahatjian provides no teaching or reasoning for modifying the

Art Unit: 1762

inflated state of the balloon during deposition. One of ordinary skill in the art would have inflated the balloon prior to deposition and would not have been concerned with the inflated state during deposition. Therefore, the inflated state of the balloon would have remained substantially the same during deposition because one of ordinary skill would not have actively modified the inflated state.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Barry '358 as applied to claim 21 above, in view of Reiss (U.S. Patent 6,913,617).

Barry is discussed above, but does not explicitly teach that paclitaxel is supersaturated in the carrier fluid.

Reiss teaches that a method of coating an implantable device (i.e., a balloon catheter), wherein a mixture of a therapeutic substance and a carrier fluid can be coated onto the device. The therapeutic substance can be supersaturated in the carrier fluid (col. 9, lines 11-25). The selection of something based on its known suitability for its intended use has been held to support a prima facie case of obviousness. *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to have coated the balloon catheter of Barry with a supersaturated solution of paclitaxel in a carrier fluid with a reasonable expectation of success because Reiss teaches that coating a supersaturated solution of a therapeutic device is suitable in the art of implantable medical devices.

10. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Barry '617 as applied to claim 21 above, view of Boulais (U.S. Publication 2004/0213893).

Barry teaches that a polyurethane coating (i.e., a porous membrane) can be deposited on the surface of the balloon, but does not explicitly teach an inner non-porous layer and an outer porous layer.

Boulais teaches that a balloon catheter can be coated with multiple layers of different polymer materials, such as polyurethanes and polylactic acid (i.e., a non-porous material) [0008]-[0009]. The Applicant teaches that polylactic acid is one of the preferred non-porous materials used as the wall membrane (pg. 7, 1st full paragraph). The selection of something based on its known suitability for its intended use has been held to support a *prima facie* case of obviousness. *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to have had an inner polylactic acid layer and an outer polyurethane layer on the balloon surface of Barry with a reasonable expectation of success because Boulais teaches that multiple layers of different polymer materials can be coated on the surface of a balloon catheter and that such polymers are suitable materials for coating a balloon catheter.

11. Claims 1, 5, 8-9, 19, and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reiss et al. (U.S. Publication 2003/0032963).

Reiss discloses a method for coating a balloon. The balloon can have a catheter [0050]. The balloon can be wholly inflated before applying a therapeutic drug to coat the balloon [0201]. The balloon can be deflated and then allowed to dry [0203].

Reiss teaches that the balloon can be wholly inflated, but does not explicitly teach that the inflated state is greater than a range of an intended expanded configuration of the balloon and less than a diameter at which the balloon becomes damaged or unsuitable for use. However, an inflated state greater than a range of an intended configuration can be interpreted to be having one extra molecule of fluid more than an inflated state at its intended expanded configuration. A *prima facie* case of obviousness exists where the claimed ranges and prior art do not overlap but are close enough that one in ordinary skill in the art would have expected them to have the same properties. *Titanium Metals Corp. of America v. Banner*, 778 f.2d 775, 227 USPQ 773 (Fed. Cir. 1985). See MPEP 2144.05. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to have

inflated the balloon to an inflated state greater than a range of an intended expanded configuration as opposed to the wholly inflated state of Reiss with a reasonable expectation of success because the state of inflations are so close that one of ordinary skill in the art would have expected the balloons to have similar properties, especially in the absence of unexpected results. In addition, it would have been obvious to one of ordinary skill in the art at the time of invention to have inflated the balloon so that the balloon does not become damaged or unsuitable for its intended use of insertion into a patient because a consumer would be unlikely to purchase a damaged or unsuitable balloon and because such unsuitability would defeat the intended purpose of the balloon catheter used for insertion into a patient.

Claim 5: Reiss does not explicitly teach maintaining the inflated state at the same or generally the same level during the application of the substance to the balloon. However, Reiss provides no teaching or reasoning for modifying the inflated state of the balloon during deposition. One of ordinary skill in the art would have inflated the balloon prior to deposition and would not have been concerned with the inflated state during deposition. Therefore, the inflated state of the balloon would have remained substantially the same during deposition because one of ordinary skill would not have actively modified the inflated state.

Claim 8: The therapeutic drug is in a carrier fluid.

Claim 9: After drying, a dry form of the substance will be left on balloon.

Claim 19: The balloon is inflated prior to the coating step.

Claim 62: The balloon can be deflated [0203].

12. Claims 1, 5, 8-9, 19, 22-23, 59-62, and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barry '358 in view of Reiss et al. (U.S. Publication 2003/0032963).

Barry is discussed above, but does not explicitly teach inflating a balloon catheter assembly to an inflated state wherein the inflated state is greater than a range of an intended expanded configuration of the balloon. Barry only provides the generic teaching of inflating the balloon prior to deposition [0072].

Reiss teaches that a balloon of a catheter can be wholly inflated prior to coating. Because Barry teaches the need to inflate the balloon, it would have been obvious to one of ordinary skill

Art Unit: 1762

in the art at the time of invention to have wholly inflated the balloon of Barry with a reasonable expectation of success since Reiss teaches that such inflated states of the balloon is operable for deposition. The selection of something based on its known suitability for its intended use has been held to support a *prima facie* case of obviousness. *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945). Although Reiss does not teach inflating the balloon greater than a range of an intended expanded configuration, such would have been obvious in view of “wholly inflated”, as discussed above.

Claims 59-62: Barry is discussed above. Barry teaches that the balloon can be collapsed prior to insertion into a patient, but does not explicitly teach that the deflating can occur prior to or during the removing process. However, Reiss teaches that a coated balloon can be deflated prior to drying [0203]. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to have deflated the balloon of Barry prior to drying with a reasonable expectation of success because Barry teaches the need to deflate the balloon and because Reiss teaches that such order of steps is operable in the art. Additionally, the selection of any order of performing process steps is *prima facie* obvious in the absence of new or unexpected results. See, for instance, *In re Burhans*, 154 F.2d 690, 69 USPQ 330 (CCPA 1946). It would have been obvious to one of ordinary skill in the art at the time of invention to have deflated the balloon at any time, including prior to or during the drying process, because the Applicant has not shown that the order of steps would have unexpected results.

13. Claims 16 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reiss '963 as applied to claim 1 above, in view of Fukaya '066.

Reiss is discussed above, but does not explicitly teach that gas is blown subsequent to deposition. Reiss does teach the need to dry the coating after deposition.

Fukaya teaches a method of coating a balloon catheter, wherein the balloon is blow-dried after deposition of the coating (col. 27, lines 54-64). The selection of something based on its known suitability for its intended use has been held to support a *prima facie* case of obviousness. *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to have included a step of blow-drying in the drying process of Reiss with a reasonable expectation of

Art Unit: 1762

success because Fukaya teaches that blow-drying is a suitable method of drying a coating on a balloon catheter. In addition, one would have been motivated to do so in order to evaporate the solvent in a shorter time.

14. Claims 16 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barry '358 as applied to claim 1 above, in view of Fukaya '066 for substantially the same reasons as discussed immediately above.

15. Claims 29, 57, and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barry '358 in view of Evens et al. (U.S. Publication No. 2003/0065346).

Barry is discussed above, but does not explicitly teach that the polyurethane polymer has pores. However, Evens teaches that porous polymers such as polyurethane can be used as a biocompatible compound [0180]. Because Barry teaches that the polyurethane can be a biodegradable, bioabsorbable, or biostable polymer [0034], it would have been obvious to one of ordinary skill in the art at the time of invention to have used a porous polyurethane as the particular polyurethane of Barry since Evens teaches that such compounds are biocompatible. Barry does not explicitly teach collapsing the pores after applying the substance to the balloon. However, such must necessarily occur for substantially the same reasons as discussed above.

16. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Barry '617 in view of Evens '346 as applied to claim 29 above, and further in view of Boulais '893 for substantially the same reasons as discussed in the rejection of claim 30 above.

17. Claims 57, 59-61, and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reiss '963 in view of Evens '346.

Reiss is discussed above, but does not explicitly teach that the wall membrane of the balloon has pores. However, Reiss does teach that the material of the balloon can be polyurethane. Evens teaches that porous polymers such as polyurethane can be used as a biocompatible compound [0180]. It would have been obvious to one of ordinary skill in the art at the time of invention to have used a porous polyurethane as the particular polyurethane

Art Unit: 1762

material of the balloon of Reiss with a reasonable expectation of success because Evens teaches that such materials are well known for use in medical devices.

Reiss does not explicitly teach that collapsing the pores after applying the substance in the fluid carrier to the balloon. However, such must necessarily occur as discussed above.

18. Claims 59-61 and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barry '358 in view of Reiss '963 as applied to claim 57 above, and further in view of Evens '346 for substantially the same reasons as discussed above.

Response to Arguments

19. Applicant's arguments filed 3/29/2007 have been fully considered but they are not persuasive.

Claims 15, 21-31, 47-56, and 64 as rejected under 35 U.S.C. 112, first paragraph:

The Applicant argues on pg. 10 that deflating the balloon prior to or during the process of removal of fluid results in and, thereby supports, deflating the balloon prior to the intended use of the balloon because deflating of the balloon prior to or during the process of removal of fluid occurs before the intended use of the balloon. However, there is no support for deflating the balloon after removal of the fluid, which is encompassed in the scope of deflating the balloon in preparation for the intended use of the balloon as claimed.

The Applicant argues on pg. 10 that deflating the balloon during a process, such as in the middle of a drying time period, provides clear support for deflating the balloon after at least some of the fluid has been removed from or dried off the balloon. However, deflating the balloon after removal of at least some fluid, as claimed, also encompasses deflating after removal of all the fluid, which is not supported in the specification.

Claims 21, 24-26, 28-29, 31, 43-44, 46, 50-52, 54, 56, and 63 as rejected over Barry '358:

The Applicant argues on pg. 11 that Barry simply teaches a drug impregnated into the polymer coating that is applied to the balloon such that the drug is within the polymer coating that has been applied to the balloon and is not within the wall membrane of the balloon itself.

However, the polymer coating is interpreted to be part of the balloon wall membrane. Thus, the drug is impregnated into the wall membrane of the balloon.

The Applicant argues on pg. 11 that Barry fails to teach deflating the balloon with the polymer coating such that the drug is contained within the polymer coating. However, Example 9 of Barry teaches that the balloon is inflated prior to coating of the balloon while Fig. 1b shows that the balloon is in a completely deflated state prior to inserting into a body lumen. Additionally, it would not make sense to insert an *inflated* balloon into a human orifice when the balloon is capable of being deflated prior to insertion and then later inflated.

The Applicant traverses the Office Action's statement that "Barry does not teach inflating or deflating the balloon during the deposition or drying process. Therefore, the inflated state of the balloon must be maintained at the same or generally the same level during the drying step." The Applicant argues on pg. 12 that Barry does not prohibit inflating or deflating the balloon during the deposition step and, thus, it does not follow that the inflated state of the balloon must be maintained at the same or generally the same level during the deposition step. However, Barry provides no teaching or reasoning for modifying the inflated state of the balloon during deposition. One of ordinary skill in the art would have inflated the balloon prior to deposition and would not have been concerned with the inflated state during deposition. Therefore, the inflated state of the balloon would have remained substantially the same during deposition because one of ordinary skill would not have actively modified the inflated state.

The Applicant argues on pg. 13 that there is no teaching in Barry that the polyurethane it mentions must necessarily be porous. The Applicant has provided U.S. Patent No. 4,367,327 to show that not all polyurethanes are necessarily porous. However, Barry teaches that the therapeutic drug is impregnated into the polymer. Impregnating involves filling the interstices (i.e., pores) of a layer with a substance. Thus, the polyurethane membrane must necessarily have pores. Additionally, the Applicant relates the amount of pores to the degree of impregnation (see pg. 17, lines 1-5 of present specification), suggesting that the impregnated layer contains pores.

Claims 1, 4-5, 8-10, 15, 19, 22, 32-35, 39-40, 42, 47-50, 54, 56, 58-59, 61-62, 64 as rejected over Reiss '963:

The Applicant argues on pg. 15 that the present Application does not state that the term “greater than an intended range of expansion” is close to “wholly or partially” inflated. However, the rejection is not based on any definitions or teachings from the present specification. Rather, Reiss teaches that the balloon can be *wholly* or partially inflated prior to the deposition step. One of ordinary skill in the art would have recognized the term “wholly” inflated to be an inflation state of the balloon to a diameter or size within the range of its intended use or design, especially when used in contrast with the term “partially”. When the balloon is wholly inflated to its maximum size within the range of its intended design, the difference between such an inflated state and an inflated state greater than such a range is one extra molecule of fluid inside the balloon. Thus, these two inflated states are close enough that one of ordinary skill in the art would have expected similar results when using either state of inflation.

The Applicant argues on pg. 15-16 that the case law stating “[a] *prima facie* case of obviousness exists where the claimed ranges and prior art do not overlap but are close enough that one in ordinary skill in the art would have expected them to have the same properties” does not apply to claim 1 as it only applies to claims that expressly recite numerical ranges or limitations. However, the Applicant is incorrect because such case law is not only limited to numerical ranges but can be applied to all ranges. The inflated state of the balloon can be considered to have different ranges, as exemplified in the present specification stating “inflation of a balloon to a diameter or size within the *range* of its intended use” (pg. 7, lines 17-19) (emphasis added by Examiner). Thus, such case law can be applied to the claims.

Claims 30 and 55 as rejected over Barry ‘358 and Boulais ‘893:

The Applicant argues on pg. 18 that Boulais is directed to coating a stent, not a balloon, and teaches using a balloon to mask the inner surface of the stent when the stent is being coated. However, Boulais provides a general teaching in [0008] that “[i]t is within the scope of the present invention to apply multiple layers of polymer coating onto *a medical device*” (emphasis added by Examiner). Boulais previously exemplifies in [0002] that medical devices can be catheters and balloons. Although the abstract and Figures only deal with coating a stent, a general teaching of coating a medical device is provided and one of ordinary skill in the art

Art Unit: 1762

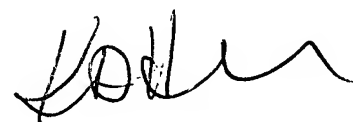
would have recognized this general teaching to apply to any medical device. The actual description of the exemplified stent does not begin until [0010], which is after the general teaching. Therefore, the teaching of Boulais is directed to the coating of medical devices, which include balloons.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jimmy Lin whose telephone number is 571-272-8902. The examiner can normally be reached on Monday thru Friday 8AM - 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tim Meeks can be reached on 571-272-1423. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JL
JL



KEITH HENDRICKS
PRIMARY EXAMINER